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SIPDIS

DEPT PLEASE PASS USTR FOR LERRION/BPEUK
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USEU FOR JULIE NUTTER AND USTR

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SUBJECT: TURKEY: PHRMA IPR ISSUES IN EU PROGRESS REPORT

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Ref: (A) Ankara 5335 and previous

¶1. (SBU) Summary: The November EU Commission Progress Report on Turkey's accession process included language about the slow movement of pharmaceutical IPR reforms. While U.S. pharmaceutical companies in Turkey have not received any new information from the Ministry of Health regarding the MOH's August 3 letter outlining which products would benefit from data exclusivity (ref A), PhRMA company representatives express guarded optimism based on the issue's inclusion in the Progress Report and another "strongly worded" letter sent by the Commission on November 6 to Turkey's EU Delegation. However, depending how the accession process proceeds after the December 15 EU Summit, PhRMA companies may call on the USG to intensify its efforts if EU influence begins to wane. End summary.

¶2. (SBU) Innovative pharmaceutical companies in Turkey, through their European trade association (EFPIA) in Brussels, have been pushing the EU Commission on three items for EU action to pressure Turkey to fully implement its data exclusivity (DE) obligations under the Customs Union. The first was that the Commission demand from Turkey's MOH a moratorium on generics approvals for the products in question until the ongoing DE issues are completely resolved. The second was that the EU send the GOT a firm letter rejecting generics claims to products filed before 1 January 2005, which covered new medicines registered in Europe between 2001 and ¶2005. Finally, PhRMA companies requested clear language in the 2006 Turkey Progress Report expressing EU concerns about DE implementation.

¶3. (SBU) In response to this pressure from EFPIA, the EU Directorate-General for Trade wrote in a November 6 letter to the GOT that, in light of the most recent list of products for which DE has been granted or rejected (ref A), the Commission is "in fact even more concerned than before on the criteria that have been applied" for processing generics applications. The letter once again urges the Turkish MOH to apply all regulatory conditions and requirements related to regulatory data exclusivity, as derived from both its international obligations, including the acquis communautaire, binding upon Turkey and from Turkish legislation. It ends by calling on Turkey to refrain from "receiving, evaluating and approving" generics applications that violate the GOT's obligations under the Customs Union rules.

¶4. (SBU) In its November Progress Report on Turkey's EU accession, the Commission included language that refers to "limited progress" in the area of pharmaceuticals and uncertainty linked to the

authorization regime applied to a number of generics, which "continues to constitute a source of concern and disagreement." PhRMA company representatives viewed this as a major victory and hope that along with the November 6 letter, it will dissuade Turkey's MOH from taking further action to approve additional generics applications from the disputed molecules.

¶5. (SBU) Comment: The questions about Turkey's EU accession have made the EU's ongoing influence on this issue more uncertain. PhRMA company representatives understand this reality and have cautioned that if EU pressure becomes less than successful, they will be looking to the USG to intensify its efforts. End comment.

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